GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1412
ANSWERED ON:26.02.2003
APPROVAL TO NEW DRUGS
N.N. KRISHNADAS

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government are aware that many new drugs are being approved without being tested on the patients adequately;

(b) if so, whether the Government have evolved any comprehensive system for continuous monitoring of the reactions of new drugs after their marketing;

(c) if so, the details thereof; and

(d) if not, the reasons therefor?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE AND PARLIAMENTARY AFFAIRS (SMT. SUSHMA SWARAJ)

(a): New drugs are approved as per guidelines given in Schedule Y of Drugsand Cosmetics Rules. As per the said guidelines, a new drug which is already approved/marketed in other countries, clinical testing is generally done on at least 100 patients distributed over 3-4 centres in the country before approval is granted for markets in this country. For a new drug discovered in India, clinical testing is done in different phases viz. Phase-I, II & III.

Some critical drugs introduced internationally for treatment of cancer, AIDS etc. are processed on fast track basis and local clinical trial generally is not insisted upon. However, the firms are required to undertaken Post Marketing Surveillance (PMS) study as per approved protocol.

(b)to(d): Through an amendment, made in Drugs & Cosmetic Rules by Notification No. GSR 900 (E) dated 12th December, 2001, it has been made mandatory to conduct P.M.S. study for new drugs allowed to be marketed in the country in order to generate adequate data on possible adverse effect on a larger population base.